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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,841	10/05/2000	Ilga Winicov	5475-US	4329

7590

09/25/2003

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,841

Applicant(s)

WINICOV, ILGA

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 are pending.
2. Applicant's election of Group II, claim 13 including SEQ ID NO:1, in Paper No. 14, filed 7/28/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is made FINAL.

Claims 1-12 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claim 13 is examined in the present office action.

Specification/Claim Objection

4. Objection is made to the specification and claim 13 for not incorporating SEQ ID NO's when referring to nucleic acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. Applicant is reminded that the drawings and Brief Description of Drawings also has to comply with the above regulation. Correction is required.
5. Applicant should amend the first line of the specification (37 CFR 1.78(a)(1)(iii)) to indicate the claimed priority. Amending the specification to recite: --This application is a

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National Stage of International Application No. PCT/US99/07902, filed on August 4, 1999, under 35 U.S.C. §371, which claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Application 60/128,083, filed July 4, 1999, and U.S. Provisional Application 60/081,348, filed August 4, 1998.-- will obviate the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, replace “shown” with --set forth-- to specifically claim Applicants’ invention.

Utility Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 13 is directed to non-statutory subject matter. This rejection is made because the claims are drawn to “An Alfalfa MsPRPs promoter” which does not indicate that the “hand of

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man" was involved in the invention. Amending the claim to recite "isolated" will obviate the rejection.

Enablement

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claim 13 is drawn to an Alfalfa MsPRP2 promoter whose sequence is shown in SEQ ID NO:1.

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Applicant has not reduced to practice the invention. Applicant presents the putative promoter sequence as SEQ ID NO:1 (page 4, line 19, Figure 4), but does not describe the isolation and verification of the promoter sequence. Applicant has only prophetically described the use of this sequence to specifically express the *Alfin1* transgene in alfalfa (page 19, lines 20-24; See also page 12 for alfalfa transformation) but Applicant has not demonstrated that the recited sequence contains all the necessary elements to specifically express genes of interest in root tissue of alfalfa or in roots of any other plant species.

Heterologous promoters do not always produce the same expression pattern in different species of plants and as such produce unexpected results. Oommenn et al (1994, The Plant Cell 6:1789-1803) teach that the alfalfa isoflavone reductase promoter exhibits a different expression pattern in tobacco as compared to the expression in alfalfa. In tobacco, the alfalfa isoflavone reductase promoter expressed in vegetative tissues and in reproductive organs whereas the same construct only expressed in the root meristem, cortex and nodules of alfalfa plants (abstract).

Using a piece of a promoter that does not contain the full complement of cis-acting elements, will not produce the expected expression profile as observed using the whole promoter fragment. Kagaya et al (1995, Mol. Gen. Genet. 248 :668-674) teach the rice chloroplastic aldolase promoter contains two elements, one of which acts as a negative element while the other acts as a positive element that confers developmentally regulated mesophyll cell specific expression. Removal of either of these regions changes the normal expression pattern (page 670, left column). Kagaya et al also teach that the promoter contains an element that serves as a target for light induction (abstract).

Given the limited guidance in the instant specification, it is not clear how one skilled in the art would use the claimed sequence to express heterologous nucleic acid sequences encoding polypeptides. Because of the lack of guidance, it is unclear in which tissues the claimed sequence directs expression or if the claimed sequence directs any expression at all. Before using the claimed sequence, one skilled in the art would have to transform a multitude of plants with Applicant's sequence and evaluate the expression profile of the claimed sequence. This procedure requires analyzing hundreds of plants, from many plant families whose transformation has not been taught in the instant application. Because of the lack of guidance as stated previously, and given the state of the art as reported above, undue experimentation would be required by one skilled in the art before the claimed sequence could be used.

9. Claim 13 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

September 15, 2003

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600